IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION ***THIS DOCUMENT RELATES TO ALL CASES***	**MDL NO. 16-2738 (FLW) (LHG)**

DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE EXPERT OPINIONS OF GHASSAN SAED

DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability Partnership
600 Campus Drive
Florham Park, New Jersey 07932
(973) 549-7000

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
(202) 371-7000

Attorneys for Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.

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Faced with prominent cancer researchers from NYU, the University of Alabama, Johns Hopkins, the University of Vermont and the Miami Cancer Institute, all of whom found Dr. Saed's experiments and conclusions to be highly flawed, scientifically impossible, ridden with error and potentially fraudulent, plaintiffs' brief essentially retracts many of Dr. Saed's opinions, including, most notably, his claim that he induced genetic mutations in 72 hours. Plaintiffs also:

- Contend that Dr. Saed has not attempted to demonstrate causation, even though Dr. Saed's report expressly opines that his work shows that "Johnson's Baby Powder exposure can cause ovarian cancer";[1]
- Ignore that Dr. Saed deemed it "***critical***" to perform a neoplastic transformation assay in order to support a causal conclusion – an assay he never performed;
- Argue that Dr. Saed had no predetermined conclusions, while failing to address the fact that Dr. Saed expressly stated that he "***expect[ed]***" that he would achieve results favoring plaintiffs in the budget document he prepared before he began his experiments; and
- Ignore the fact that Dr. Saed's published article falsely claims that he "received no financial support" for the article even though plaintiffs' counsel paid him between $36,000 and $42,000 to write it.

These full-scale retreats from the opinions offered by Dr. Saed are reason enough to exclude his testimony. Dr. Saed's opinions must be measured against their own logic, not counsel's post hoc reimagining of those opinions for purposes of attempting to survive a *Daubert* challenge. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d

[1] (Expert Report of Ghassan Saed, Ph.D. ("Saed Rep.") at 20, Nov. 16, 2018 (attached as Ex. C17 to Certification of Julie L. Tersigni ("Tersigni Cert."), May 7, 2019 (ECF No. 9723-2)).)

665, 672-73 (6th Cir. 2010) (rejecting counsel's effort to redefine the expert's opinion; the expert's "opinion cannot escape its own logic").

Even as to the Saed opinions that plaintiffs do choose to defend, their arguments are completely meritless, either because they rest entirely on Dr. Saed's *ipse dixit* assertions or because they rely on plaintiffs' counsel's own unsupported assertions. Plaintiffs' weak defense of Dr. Saed only serves to underscore the case for excluding his opinions, for several reasons.

First, Dr. Saed's opinions were made for litigation and suffer from a multitude of serious methodological flaws. In response, plaintiffs offer a highly formalistic argument regarding the factors that courts generally consider under *Daubert*, insisting that, because others have ostensibly undertaken similar experiments in the published literature, the Court should unquestioningly accept Dr. Saed's work. But Dr. Saed's endeavor was unscientific from the outset, because he reached conclusions before his experiments began, abandoned his own prescribed methods for trying to validate those conclusions, and departed from basic scientific principles at every step of his experiment and analysis.

Second, even if Dr. Saed's methods and results were unassailable, they would still fail to make either causation or biological plausibility any more likely because there is no evidence that his findings relate to ovarian carcinogenesis in humans. Plaintiffs attempt to sidestep this problem by insisting that Dr. Saed need

not prove causation. But this argument glosses over the significant gap that remains between Dr. Saed's findings and bare biological plausibility. Dr. Saed himself acknowledged that he would need to conduct animal studies to ensure that his results had any relevance to humans, and plaintiffs do not even attempt to respond to the fact that there are no scientific data supporting the notion that Dr. Saed's claimed SNP and CA-125 findings are relevant to ovarian carcinogenesis, presumably because they do not have the scientific background to rebut the opinions of world-renowned cancer researchers, who have explained that these findings are meaningless.

Third, Dr. Saed's manipulation of the peer-review process further warrants exclusion. Plaintiffs attempt to deflect on this score by pointing to the alleged "peer-review" process involved in the publication of Dr. Saed's numerous abstracts. But such review is not rigorous and is essentially meaningless under *Daubert* because, as defendants' expert Dr. Benjamin Neel put it, acceptance of an abstract, even by five reviewers, generally signifies little more than the fact that "it was probably written in English."[2] This characterization is fully borne out by Dr. Saed's published abstracts, which, as he admitted, contained errors that the reviewers did not detect. And the fact remains that neither these reviewers nor the

[2] (Dep. of Benjamin G. Neel, M.D., Ph.D. ("Neel Dep.") 341:7-10, Mar. 19, 2019 (attached as Ex. B6 to Tersigni Cert.).)

reviewers at the publications that considered Dr. Saed's manuscript were ever informed that he was paid hundreds of thousands of dollars by plaintiffs' counsel for his work and for writing the manuscript.

ARGUMENT

I. DR. SAED DID NOT APPLY A RELIABLE METHODOLOGY.

Plaintiffs' attempt to shore up Dr. Saed's opinions based on the legal standard governing admissibility lacks merit. Plaintiffs' defense begins with an invocation of eight factors relating to reliability set forth in *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994). While plaintiffs initially acknowledge that the list is "non-exclusive" and that a *Daubert* motion is not evaluated by simply "tally[ing] . . . how many of them end up in a party's favor," they then proceed to tally them as though they were the only relevant considerations.[3]

The Court should reject this exceedingly formalistic analysis. Courts are not bound to evaluate *Daubert* challenges according to *Paoli*'s eight factors, but are instead "entrusted to examine the reliability of the proffered expert testimony in a flexible manner." *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 656 (D.N.J. 2008); *see also Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 152 (3d Cir.

[3] (Pls.' Steering Committee's Mem. of Law in Resp. & Opp'n to Defs.' Mot. to Exclude Expert Ops. of Ghassan Saed ("Pls.' Opp'n") at 19, May 29, 2019 (ECF No. 9875); *see also id.* at 18-22.)

1999) ("[T]he factors are simply useful signposts . . . ."). In *Heller*, for example, the Third Circuit affirmed exclusion of an expert's causation opinion based on his unreliable assessment of the temporal connection between alleged exposure and illness – not pursuant to a rigid analysis of the *Paoli* factors, but through a logical assessment of the expert's reasoning based on the facts in the record. *See* 167 F.3d at 157-58. Defendants' opening brief offered such a logical assessment and also relied on other *Daubert* decisions that have excluded expert opinions exhibiting flaws similar to those of Dr. Saed's. *Paoli* requires nothing more.

In any event, many of the issues that defendants have raised do correlate with the factors enumerated in *Paoli*. With respect to "error rate," for example, defendants' opening brief highlights significant errors in Dr. Saed's math and his SNP results, and explains how his failure to perform his experiment in triplicate is unscientific precisely because it obscures his potential rate of error.[4] *Cf.*, *e.g.*, *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 570 (W.D. Pa. 2003) (when a proposed expert "cannot define or defend a rate of error," his "failure . . . even to address this major *Daubert* factor counsels strongly against [the] admissibility of his opinions"). Defendants also addressed the issue of peer review, dedicating an

[4] (*See* Defs.' Mem. of Law in Supp. of Defs.' Br. to Exclude Expert Ops. of Ghassan Saed ("Defs.' Br.") at 41-43, May 7, 2019 (ECF No. 9736-2) (failure to perform experiment in triplicate), 46-52 (unreliability of SNP results), 52-55 (mathematical errors).)

entire section of their opening brief to the issue and demonstrating that Dr. Saed subverted the peer-review process, which further supports exclusion of his opinions.[5]

Moreover, plaintiffs' narrow focus on *Paoli*'s eight factors blinds them to the fact that an expert must not only identify a reliable methodology, but also apply that methodology reliably. *See Paoli*, 35 F.3d at 745. Thus, it would not suffice, even if true, that Dr. Saed identified and claimed to employ standard methods because he did not execute those methods reliably. *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017) ("Both an

[5] In reality, and for reasons encapsulated in the arguments set forth in defendants' briefing, none of the *Paoli* factors (which are set forth in Pls.' Opp'n at 19) favors admission of Dr. Saed's opinions. The first is whether his method involved a testable hypothesis, Dr. Saed did not form actual hypotheses, instead offering predetermined conclusions, as further addressed in Part I.A, below. The second and third factors relate to peer review and rate of error, which are addressed above. The fourth and sixth factors concern the existence of standards controlling a technique's operation and to what extent methods have been established as reliable, but as elaborated in Parts I.B, D, E and H, Dr. Saed failed to adhere to such standards by departing from his own stated methodology, failing to use adequate controls or performing tests in triplicate, and departing from the most rudimentary requirements governing the maintenance of lab notebooks. The fifth factor – general acceptance – is not met here because, among other things, Dr. Saed did not even attempt to reconcile his results with the generally accepted view that talc is not genotoxic. The seventh factor, which asks about the qualifications of the expert with respect to the method at issue, also supports exclusion because Dr. Saed had never conducted tests with talc (or indeed any particulate matter) previously. And the last factor – "non-judicial uses" – also supports exclusion because Dr. Saed's experiment was conceived entirely for litigation purposes.

expert's methodology and the application of that methodology must be reviewed for reliability.")

In short, the serious flaws in Dr. Saed's methodology that are identified in defendants' opening brief and elaborated further below go directly to the issue of reliability and admissibility, and they all point toward exclusion of Dr. Saed's opinions under *Daubert*.

A. Dr. Saed Predetermined His Conclusions In Order To Serve Plaintiffs' Litigation Needs.

As shown in defendants' opening brief, Dr. Saed formulated his opinions before he began his work, as is evident in his Proposal, which expressly states that he expected to achieve the results that plaintiffs' counsel were seeking, even though he had no prior experience working with talc. Plaintiffs respond by contending that Dr. Saed's opinions were not "made-for-litigation" or "predetermined."[6] These arguments lack merit.

As a threshold matter, plaintiffs' contention that Dr. Saed's opinions could not have been "made-for-litigation" because he has been studying "oxidative stress in the pathogenesis of ovarian cancer for nearly 30 years" exaggerates Dr. Saed's experience and, in any event, misses the point.[7] The relevant issue is not merely

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[6] (Pls.' Opp'n at 22-28.)

[7] (*Id.* at 22-25.) Dr. Saed's resume does not support the claim that he has studied oxidative stress in the pathogenesis of ovarian cancer for anything close to *(cont'd)*

that Dr. Saed developed opinions for litigation, but that he reached conclusions intended to serve litigation purposes before he even conducted the experiments that could tell him whether those conclusions were correct.[8]

Plaintiffs do not even attempt to argue that such conclusion-driven work could pass muster under *Daubert*. Instead, they assert that Dr. Saed did not predetermine his conclusions, and instead merely formulated hypotheses. That is not correct. As noted in defendants' opening brief, Dr. Saed prepared a Proposal that outlined the three "Aims" of his experiments, and under each Aim, he set

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30 years. His first appointment to an obstetrics and gynecology position was in 1998. (Saed Rep. Ex. A, at 2.) Prior to this appointment, he was involved in dermatology and hypertension research, among other positions. (*Id.*) The first grant he lists on his CV having anything to do with ovarian cancer was awarded for 2008-09. (*Id.* at 19.) And the earliest publication Dr. Saed lists that mentions "ovarian cancer" in the title was from 2002. (*Id.* at 38.) In any event, Dr. Saed's published work on cancer and oxidative stress has focused on cells that are already cancerous (and particularly chemoresistance) – not on carcinogenesis. (*See id.* at 27-32.) Moreover, to the extent this prior work addressed cancer risk, it expressly disclaimed any relationship between many of the SNPs at issue here and ovarian cancer risk, as Dr. Saed begrudgingly admitted at his deposition. (*See* Dep. of Ghassan Saed, Ph.D. Vol. 1 ("Saed 1/23/19 Dep.") 211:6-225:15, Jan. 23, 2019 (attached as Ex. B12 to Tersigni Cert.).)

[8] Plaintiffs also contend that Dr. Saed's research was not made for litigation because he bore his own costs. (Pls.' Opp'n at 23.) This is misleading at best. While Wayne State University did cover some of the costs of this experiment, plaintiffs' counsel has paid Dr. Saed hundreds of thousands of dollars. (*See* Saed 1/23/19 Dep. 20:12-14, 21:21-22:3, 22:25-23:2.)

forth, in bold and italic typeface, his "***[E]xpect[ed]***" results, each one of which was aligned with plaintiffs' litigation goals.[9]

Plaintiffs do not even acknowledge Dr. Saed's "***Expect[ations]***," and their failure to do so is fatal to their argument. Such express expectations are not "hypotheses"; rather, where an "experiment appears to have been undertaken more to bolster a conclusion than to test a hypothesis," it is outcome-oriented in a manner that weighs heavily against its admission. *Benkwith v. Matrixx Initiatives, Inc.*, 467 F. Supp. 2d 1316, 1325 (M.D. Ala. 2006); *see also McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1120 (D. Or. 2010) (excluding expert "opinion developed for purposes of litigation, . . . intended to support [a litigation] opinion . . . [and] designed and conducted during the course of litigation" despite expert's testimony that he lacked any "preconceived opinion"); *Black v. Rhone-Poulenc, Inc.*, 19 F. Supp. 2d 592, 598 (S.D. W. Va. 1998) (noting that it is bad science to presume "there [is] at least some effect" before beginning research).

That Dr. Saed had "***expect[ations]***" about the results of his experiments in advance is all the more suspect and indicative of a preconceived opinion because he had no basis in experience to have expectations about how talc treatments

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[9] (Defs.' Br. at 32; The role of talc powder exposure in ovarian cancer: mechanist approach ("Proposal") at 2-3 (Ex. 44 to Dep. of Ghassan Saed, Ph.D. Vol. 2 ("Saed 2/14/19 Dep."), Feb. 14, 2019) (attached as Ex. B25 to Tersigni Cert.).)

would affect cells. As even the source on which plaintiffs rely explains, a true hypothesis is an "***educated*** guess" that arises as a result of "background research."[10] Here, Dr. Saed had done no relevant background research before expressing his "***expect[ations]***" in his Proposal. After all, he had never run an experiment using talc,[11] or, for that matter, involving application of foreign particles of any kind to cell cultures.[12] In short, there was simply no reliable basis for Dr. Saed's "***expectations***"; rather, he was communicating a desire to reach particular conclusions that he believed would advance his benefactors' interests.

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[10] *See* Helmenstine, "6 Steps of the Scientific Method," Thought Co., https://www.thoughtco.com/steps-of-the-scientific-method-p2-606045 (last updated Sept. 2, 2018) (emphasis added) (attached as Ex. A186 to 2d Suppl. Certification of Julie L. Tersigni ("2d Suppl. Tersigni Cert.")) (cited in Pls.' Opp'n at 26 & n.91). The source plaintiffs cite for this proposition appears to be a resource intended for children, underscoring the elementary nature of the principles to which Dr. Saed has failed to adhere.

[11] (*See* Saed 1/23/19 Dep. 27:12-15.)

[12] (*See id*. 62:16-23 (admitting he had never done any studies with foreign particles applied to cell cultures).) While plaintiffs make reference to Dr. Saed's "pilot experiment" (Pls.' Opp'n at 5), they leave out the fact that this study was conducted on September 26, ***after*** Dr. Saed had already prepared his Proposal and delivered it to plaintiffs' counsel. (Saed 1/23/19 Dep. 58:20-22 (agreeing that "[t]he first date of any study that [he] did with talc is September 26, 2017").) And while plaintiffs' brief elsewhere cites to prior studies by Shukla, Buz'Zard and Akhtar as general precedent for Dr. Saed's methods (*e.g.*, Pls.' Opp'n at 23-24), Dr. Saed's Proposal does not cite Shukla or either of the Akhtar studies at all, and while it does cite to the Buz'Zard study, it does so only in support of the neoplastic transformation assay he never performed. (*See* Proposal at 3, 7 (reference 27).)

B. Dr. Saed Did Not Follow His Own Methodology.

As defendants explained in their opening brief, Dr. Saed set out a methodology that he believed would be necessary to show that talcum powder could contribute to the development of ovarian cancer – and then failed to follow through on it. This alone merits exclusion of his opinions.

Plaintiffs do not seriously dispute that a failure to follow one's own methods weighs against a finding of reliability,[13] but instead contend that Dr. Saed did follow his own stated methodology, or at least came close enough. According to plaintiffs, Dr. Saed proposed redundant tests under each of his three Aims, and therefore "did not necessarily need to perform each and every [test] – he picked the 'most key one.'"[14] This argument fails on its own terms. As explained in defendants' opening brief, Dr. Saed did not conduct the neoplastic transformation assay that (in his own words) was the "***critical***" test under his Aim 3; nor did he test for BRCA 1 or 2 in his tests for SNP mutations, even though these SNPs

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[13] Plaintiffs cite no cases of their own in the relevant section of the brief, and although they halfheartedly, and by footnote, attempt to distinguish some of the cases defendants cited, they fail to do so. For instance, plaintiffs remarkably contend that *Soldo*, 244 F. Supp. 2d at 560 (cited in Pls.' Opp'n at 31 n.106), is only about subjectivity and not an expert's failure to follow his stated methodology, when in fact an entire section of the court's decision is entitled "Plaintiff's Experts Fail to Faithfully Apply Their Own Scientific Standards" and states time and time again that the experts' "significant departures from their own standards render their methodolog[ies] scientifically unreliable," 244 F. Supp. 2d at 560.

[14] (Pls.' Opp'n at 29.)

(unlike the ones he did test for) have actually been associated with ovarian cancer in genome-wide association studies.[15] In short, Dr. Saed did in some sense "pick[] the 'most key'"[16] tests in his Proposal, but he picked them for ***exclusion***, not inclusion, rendering his methods unreliable.

With respect to Aim 3, plaintiffs further suggest that because Dr. Saed's showing of increased cellular proliferation and decreased apoptosis should suffice to demonstrate that talc "could be reasonably expected to contribute to the initiation and pathogenesis of ovarian cancer," he did not need to perform his proposed test for neoplastic transformation.[17] But defendants already demonstrated that Dr. Saed's proliferation and apoptosis tests could not stand in for the neoplastic transformation testing that he himself deemed "***critical***" to establishing causation.[18] Proliferation and apoptosis can indicate a number of normal biological processes. As Dr. Saed himself acknowledged at his deposition,

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15 (Defs.' Br. at 12; *see also* Proposal at 2-3.)

16 (Pls.' Opp'n at 29 (quoting Saed 2/14/19 Dep. 499:1).)

17 (Pls.' Opp'n at 30.)

18 Notably, Dr. Saed did not even conduct the proliferation assay that he specified in his Proposal, which was to test for proliferation in cells suspended in soft agar, as was done in the Buz'Zard study that plaintiffs repeatedly cite as a purported model for Dr. Saed's work. (*See* Saed 2/14/19 Dep. 503:10-19 (explaining that he did not conduct an agar test because of "[e]xpense").) This departure is one more illustration of Dr. Saed's disregard of his own methods and those reported in the published literature.

for example, proliferation is "a normal response of all normal cells to agents,"[19] and he knew of no study linking cell proliferation to the development of cancer.[20] In short, alterations in cell proliferation and apoptosis are not uncommon and thus cannot be taken as proof of neoplastic transformation.[21]

Plaintiffs do not even attempt to respond. Instead, they simply posit that "the data presented" by Dr. Saed "could reasonably be expected to contribute to the initiation and pathogenesis of ovarian cancer."[22] But plaintiffs do not explain why changes in proliferation or apoptosis could be expected to cause or contribute to the development of cancer, much less cite any literature, testimony or legal authority in support of this assertion. Of course, the Court cannot accept an opinion "connected to existing data only by the *ipse dixit* of the expert," *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); it follows perforce that it cannot accept an opinion connected to the existing data only by the *ipse dixit* of parties and their counsel.

Plaintiffs also assert that the peer reviewers at *Gynecologic Oncology* and *Reproductive Sciences* did not raise concerns about Dr. Saed's methods.[23] This

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19 (Saed 1/23/19 Dep. 265:12-17 (quoted in Defs.' Br. at 65).)

20 (*Id.* 268:10-269:4 (quoted in Defs.' Br. at 65 n.159).)

21 (Defs.' Br. at 34 n.103; *id.* at 64-65.)

22 (Pls.' Opp'n at 30.)

23 (Pls.' Opp'n at 30-31.)

argument makes no sense. Dr. Saed did not produce his original Proposal when he submitted his article for publication; as a result, the peer reviewers had no way to know whether or not he followed the methodology he laid out in it. Moreover, even without the benefit of knowing that Dr. Saed had eschewed tests he had deemed "***critical***," the *Gynecologic Oncology* reviewers essentially did catch his omission, stating that the "data do not show, despite the authors' claim, any evidence that these cells are transformed."[24]

In short, plaintiffs' efforts to justify Dr. Saed's sharp departures from his own prescribed methods only further underscore their problematic nature. Such departures should raise red flags under *Daubert* because they suggest the possibility that the expert knew or suspected that he would not like the results that those tests would show, especially in the absence of a good reason for not doing them. Although Dr. Saed cited "expense"[25] as a basis for not completing the additional work, that explanation makes no sense given the hundreds of thousands of dollars he was paid to serve as an expert and the absence of any documentation

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[24] (Email from *Gynecologic Oncology* to Ghassan Saed, Ph.D. et al re GYN-18-1020: Final Decision, at 2 (May 19, 2018) ("Rejection Letter") (Saed 2/14/19 Dep. Ex. 35) (attached as Ex. B23 to Tersigni Cert.); *see also id.* ("[T]he present data are insufficient to back up the claim that talc[] is central to the development of ovarian cancer.").)

[25] (Saed 2/14/19 Dep. 501:14-502:24, 503:10-19, 505:14-20 (attached as Ex. B19 to Tersigni Cert.).)

from his university denying requests for funding. For these reasons, too, the Court should exclude his opinions.

C. Dr. Saed Failed To Use A Relevant Dose, Rendering His Conclusions All The More Unreliable.

Defendants' opening brief also demonstrated that Dr. Saed's opinions are unreliable because he did not even attempt to establish a relevant dose for his experiments.[26] Without citing any authority for support, plaintiffs assert that "[d]etermination of a relevant dose was not necessary" because Dr. Saed ostensibly opines on biological plausibility rather than causation and, in any event, the doses he used compare with those used in other literature.[27] These arguments lack merit.

First, plaintiffs' contention that Dr. Saed need not worry about dose in the context of an opinion limited to biological plausibility misconstrues Dr. Saed's opinion, misstates the law, and defies common sense. As an initial matter, Dr. Saed's opinions go beyond biological plausibility. There is no ambiguity in his

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[26] (Defs.' Br. at 35-37.) As discussed in defendants' Motion To Exclude Plaintiffs' Experts' Opinions Related To Biological Plausibility ("Bio. Plaus. Br.") and the reply in support, ***no*** talc can reach the fallopian tubes or ovaries. But assuming, for the sake of argument, that some could, it is undisputed that exposure would be nothing near the dose that Dr. Saed used. (*See* Defs.' Mem. of Law in Supp. of Mot. to Exclude Pls.' Experts' Ops. Related to Biological Plausibility at 18-47, May 7, 2019 (ECF No. 9736-1).)

[27] (Pls.' Opp'n at 31-33.)

conclusion: "***Johnson's Baby Powder exposure can cause ovarian cancer***."[28] Since plaintiffs do not dispute that Dr. Saed would need to identify and test a dose relevant to perineal talcum powder use in order to support a true causation opinion, and since Dr. Saed made clear that he is offering a causation opinion, his opinion is unreliable and inadmissible for this reason alone.

In any event, plaintiffs' argument would fail even if Dr. Saed's opinion were limited to biological plausibility because biological plausibility, like causation, requires consideration of dose. For example, part of the reason the court in *Wade-Greaux v. Whitehall Laboratories, Inc.* excluded an expert's opinions that were formulated in the context of an experiment conceived for litigation is that the expert erroneously "assume[d] that dose is irrelevant" in the context of researching a human "biological mechanism." 874 F. Supp. 1441, 1462-65 (D.V.I. 1994), *aff'd*, 46 F.3d 1120 (table), 1994 WL 16973481 (3d Cir. 1994).

Wade-Greaux accords with common sense because proof that a large dose could cause biological effects does not necessarily imply that smaller doses could cause the same effects. After all, one of Dr. Saed's primary conclusions is that "the molecular effects" that he purported to observe "exhibit a clear dose response

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[28] (Saed Rep. at 20 (emphasis added); *see also id.* ("Johnson's Baby Powder . . . can result in the development and the progression of ovarian cancer.").)

pattern."[29] Indeed, plaintiffs trumpet the supposed dose-responsive nature of Dr. Saed's work when it suits them.[30] But this concept cuts both ways: if there were a dose-response relationship between talc treatment and biological effects, it would be incumbent on Dr. Saed to show that the doses he was testing bear a relationship to the likely exposure scenarios involved (if any) in perineal talc use to show plausibility that ***those*** exposure scenarios could implicate the same biological effects. As he admitted, he made no such effort.[31]

Second, plaintiffs' contention that the doses used by Dr. Saed are similar to those used in the published literature by Shukla et al., Buz'Zard & Lau, and Akhtar et al.[32] is likewise without merit because none of those studies claims to have

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29 (*Id.* at 20.)

30 (*See* Pls.' Opp'n at 34 (arguing Dr. Saed's study should be credited because "[t]he treated cells were . . . exposed to different doses of talcum powder to determine a dose-response") (emphasis omitted); *id.* at 37-39 ("multiple dose treatments . . . undercuts [d]efendants' arguments against reproducibility"); *id.* at 48 ("dose-response relationship must be considered") (quoting Green et al., Fed. Judicial Ctr., *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 549, 564-65 (3d ed. 2011) ("Epidemiology Reference Manual") (attached as Ex. A51 to Tersigni Cert.)); Pls.' Steering Committee's Mem. of Law in Resp. & Opp'n to Defs.' Mot. to Exclude Pls.' Experts' Ops. Related to Biological Plausibility at 31, May 29, 2019 (ECF No. 9890) (arguing that Saed's "dose-responsive" results show biological plausibility).)

31 (*See* Defs.' Br. at 36-37.)

32 (*See* Pls.' Opp'n at 32 (referencing Shukla et al., *Alterations in Gene Expression in Human Mesothelial Cells Correlate with Mineral Pathogenicity*, 41(1) Am. J. Respir. Cell. Mol. Biol. 114 (2009) (emphasis omitted); Buz'Zard & Lau, *Pycnogenol® Reduces Talc-Induced Neoplastic Transformation in Human*

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shown a biological mechanism by which talc could cause ovarian cancer. The Shukla study showed ***no*** relationship between talc and changes in gene expression, and if a large dose showed no effect, it follows that a small dose would not, either.[33] The other studies used larger doses than Dr. Saed according to plaintiffs, but this, too, is of no moment because the authors of the Akhtar and Buz'Zard studies refrained from making anything like the claims that Dr. Saed makes in his expert report. Buz'zard and Lau went only so far as to posit that "talc ***may*** contribute to ovarian carcinogenesis" through "aberrant ROS generation,"[34] while Akhtar and his colleagues examined cell toxicity, not carcinogenesis (and in any

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Ovarian Cell Cultures, 21 Phyother. Res. 579 (2007) ("Buz'Zard & Lau 2007") (attached as Ex. A16 to Tersigni Cert.); Akhtar et al., *Cytotoxicity and Apoptosis Induction by Nanoscale Talc Particles from Two Different Geographical Regions in Human Lung Epithelial Cells*, 29 Environ. Toxicol. 394 (2012)); *see also* Pls.' Opp'n at 8 & n.30 (citing Dep. of Michael Birrer, M.D., Ph.D. 359:18-361:5, Mar. 9, 2019) (contending in part that defense expert Dr. Birrer acknowledged that the doses Dr. Saed used have been used in the peer-reviewed literature).)

[33] Moreover, plaintiffs provide no evidence to support the claim that the Shukla study used a similar dose of talc, instead simply asserting that the concentrations in the two studies are "comparative . . . when conversions are done." (*See* Pls.' Opp'n at 32 & n.109; Dep. of Brooke T. Mossman, M.S., Ph.D. 358:4-18, Apr. 8, 2019 (attached as Ex. B7 to Tersigni Cert.) (explaining the surface area concentrations of talc used in the Shukla study).) With no support for this argument, it is simply their say-so.

[34] *See* Buz'Zard & Lau 2007 at 586 (emphasis added).

event studied "nanotalc" particles, which the authors suspected could pose unique hazards on account of their "nano-size").[35]

For these reasons, too, Dr. Saed's opinions lack a reliable basis, regardless of whether those opinions sound in causation or biological plausibility.

D. Dr. Saed Failed To Use Appropriate Controls.

As defendants' opening brief explained, Dr. Saed failed to use adequate controls in his study, both by using DMSO as a solvent without taking steps to ensure that it would not interfere with his results and by failing to use negative controls like cornstarch or glass beads.[36] Plaintiffs appear to agree that failing to use a proper control would provide a basis for the exclusion of an expert opinion based on an experiment,[37] but contend that: (1) DMSO is a proper solvent; (2) there was no need to use glass beads or any other negative control; and (3) there is no evidence that talc would interfere with colorimetric assays. These arguments lack merit.

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35 Akhtar et al., *The Primary Role of Iron-Mediated Lipid Peroxidation in the Differential Cytotoxicity Caused by Two Varieties of Talc Nanoparticles on A_{549} Cells and Lipid Peroxidation Inhibitory Effect Exerted by Ascorbic Acid*, 24 Toxicol. in Vitro 1139, 1140 (2010) (attached as Ex. V to Pls.' Opp'n).

36 (Defs.' Br. at 37-41.)

37 Plaintiffs certainly cite no contrary authority, and their limited arguments regarding defendants' cases only seek to differentiate Dr. Saed's work, not to dispute the premise that adequate controls are necessary. (*See* Pls.' Opp'n at 37 & n.124.)

First, plaintiffs' contention that there is no evidence that DMSO could have "skewed the results of Dr. Saed's experiments"[38] is wrong. Defendants' brief did identify evidence that DMSO could have skewed Dr. Saed's results, specifically pointing to recent research calling the use of DMSO into question. Defendants also highlighted results from Dr. Saed's own experiments, which showed that DMSO "supernatant" – which is DMSO with talc particles removed – produced similar detectible effects on cells, meaning that either the DMSO itself or some interaction between DMSO and the talc previously dissolved in it was affecting the cells, contradicting the notion that DMSO is a neutral control.[39] Plaintiffs do not even attempt to explain the supernatant results, which is evidence from Dr. Saed's own work that should have prompted questions about DMSO's suitability.

With respect to the literature, plaintiffs assert that Dr. Boyd acknowledged that it does not apply because he "agree[d] that DMSO is a 'virtual, universal solvent'" and he does not specifically know whether DMSO interacts with talc.[40] This argument mischaracterizes Dr. Boyd's testimony. Dr. Boyd's agreement that DMSO is a "universal" solvent meant only that DMSO can dissolve many things and has been chosen in the past because of that characteristic – as Dr. Boyd

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38 (*Id.* at 34.)

39 (Defs.' Br. at 39.)

40 (Pls.' Opp'n at 35.)

explained in a portion of the deposition that plaintiffs omit.[41] And as Dr. Boyd further explained, while existing literature focused on DMSO's interactivity with chemotherapeutic drugs, there is no reason to believe the problems would be limited to that context, especially since talc has elemental commonalities with chemotherapeutic agents.[42] Finally, it is notable that while plaintiffs rely on the studies by Shukla, Buz'Zard and Akhtar for a number of other propositions in their opposition, all of these studies dissolved talc in other solvents, such as HBSS or culture media.[43]

Second, plaintiffs' assertion that Dr. Saed did not need to use any negative control[44] also lacks merit. Much of plaintiffs' argument on this score relates to the suitability of glass beads specifically as a negative control, but defendants' argument does not turn on this; indeed, the opening brief also suggested "cornstarch or other inert substances" as possible negative controls.[45] The use of a

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41 (Dep. of Jeffrey A. Boyd, Ph.D. ("Boyd Dep.") 236:9-15, Apr. 8, 2019 (attached as Ex. Y to Pls.' Opp'n) (Q. "Okay. Do you agree that DMSO is a virtual, universal solvent?" A. "I believe that [DMSO] is used very commonly to dissolve chemicals of all kinds in an experimental context because many chemicals are readily soluble in DMSO.").)

42 (Boyd Dep. 244:2-245:6.)

43 This fact is especially striking in light of Dr. Saed's initial claim at his deposition that he had gotten the idea to use talc "from . . . other papers," none of which he identified. (Saed 2/14/19 Dep. 433:8-22.)

44 (Pls.' Opp'n at 36.)

45 (Defs.' Br. at 39.)

negative control was important in this instance to confirm that what drove Dr. Saed's reported results were characteristics unique to talc rather than particulate matter generally.[46] Plaintiffs contend that other studies – including Buz'Zard and Akhtar – did not use negative controls,[47] but these articles also do not make the sweeping claims Dr. Saed makes, as previously noted. Plaintiffs also contend that no reviewers pointed out Dr. Saed's failure to use negative controls,[48] but the *Gynecologic Oncology* editors did challenge Dr. Saed's causal conclusions,[49] and as defendants have previously argued, it is unclear that the *Reproductive Sciences* reviewer had the expertise needed to critically assess Dr. Saed's claims.[50]

Third, plaintiffs' assertion that defendants offered no proof that talc could interfere with the assays that Dr. Saed used to measure enzymatic activity[51] also lacks merit. Again, this argument incorrectly assigns defendants a burden they do not have. It also ignores the evidence that defendants did offer in their opening brief that the assays Dr. Saed used measure changes in color as a way to determine

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46 Plaintiffs implicitly acknowledge this point in arguing that "[t]here is no literature to suggest that ***tissue does not react*** to glass beads." (Pls.' Opp'n at 36 (emphasis added).)

47 (*Id.*)

48 (*Id.* at 36-37.)

49 *See* Part I.B, above.

50 (*See* Defs.' Br. at 49 n.130.)

51 (Pls.' Opp'n at 35.)

changes in protein activities and that particulates like talc can interfere with the interpretation of these assays and skew the results.[52] Specifically, defendants identified evidence from Dr. Moore, who attested that particulates like talc can interfere with the assays that Dr. Saed used, and from Dr. Saed's own lab notes, which indicate an awareness that talc could affect measurements.[53] Plaintiffs argue that such interference did not happen, relying on Dr. Saed's own *ipse dixit* assurance at his deposition that his methods for washing the cells prior to testing were sufficient to remove particulate matter and prevent interference with the assays.[54] As noted above, such assurances do not suffice. Because, as Dr. Saed admitted, he had never previously conducted an experiment like this one involving treatment of cells with particulates,[55] Dr. Saed needed to take additional steps to ensure that contamination was not an issue. Because he did not do so, he failed to ensure reliable results, further rendering his opinions inadmissible.[56]

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52 (Defs.' Br. at 40-41.)

53 (*Id.* at 41 & nn.115, 117.)

54 (Pls.' Opp'n at 35-36.)

55 (Saed 1/23/19 Dep. 62:4-23.)

56 Plaintiffs cite no cases in support of their arguments. They attack defendants' cases as ostensibly distinguishable, but the only differences they identify in these cases are different problems with controls. (*See* Pls.' Opp'n at 37 & n.124.) They do not dispute the fundamental premise that proper controls are required as a matter of reliable science. And while plaintiffs point out that *Wade-Greaux* did not exclude experts for failure to include a proper control group (*id.*),

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E. Dr. Saed Failed To Demonstrate That His Results Were Reproducible Through Proper Triplicate Testing.

As explained in defendants' opening brief, Dr. Saed's opinions are also unreliable because he tested each talc concentration/cell line combination just one time, instead of using proper triplicates.[57] Plaintiffs attempt to excuse Dr. Saed's failure to reproduce any part of his experiment by pointing to the fact that he tested six cell lines and that each cell line was subjected to multiple different doses of talc. This argument fails because it departs from scientifically accepted methods for running experiments in triplicate.

Plaintiffs' proffered stand-in for real triplicate work – the repetition of the same experiment across "multiple cell lines" and "multiple doses" – is exactly what the court rejected in *Rovid v. Graco Children's Products Inc.*, No. 17-cv-01506-PJH, 2018 WL 5906075 (N.D. Cal. Nov. 9, 2018), on which defendants relied in their opening brief.[58] In *Rovid*, the expert tested mattresses, and the

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they ignore that defendants cited the case for an entirely different proposition: the ability of sufficiently large doses of any substance to induce cellular changes.

[57] (Defs.' Br. at 41-43.)

[58] (Defs.' Br. at 42.) Plaintiffs again cite no cases of their own. They claim that *Rovid* can be distinguished because the expert only performed a single test. But Dr. Saed also only performed a single test as to each cell line/dose combination. Plaintiffs also contend that *Avon Products, Inc. v. S.C. Johnson & Son, Inc.*, 984 F. Supp. 768 (S.D.N.Y. 1997) (Sotomayor, J.) (cited in Defs.' Br. at 43), can be distinguished because it involved a test that took place "***outside the lab***." (Pls.' Opp'n at 39 & n.131 (citing 984 F. Supp. at 787).) But the court in

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plaintiffs contended that the fact that tests were run on 42 mattresses obviated the need for triplicate testing of any one mattress. *Id.* at *5-6. The court rejected this argument, explaining that because "[e]ach of the 42 mattresses tested [is] different, repetition requires the test to be run on ***each*** mattress multiple times." *Id.* at *6. Likewise here, Dr. Saed's test of three different doses and one control on six different cell lines does not suffice; each treatment was unique, and thus needed to be replicated in triplicate in order to provide some assurance that his findings were reproducible and not the result of variations in experimental procedures.[59]

In any event, even if consistency across cell lines and doses would suffice to substitute for triplicate testing as a general matter, in Dr. Saed's case, it only further undermined the reproducibility of his results because his findings were ***inconsistent*** across cell lines. For example, Dr. Saed reported that the *CAT* mutation was only detected in four out of six cell lines (not A2780 or SKOV3

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Avon never suggested that this fact was relevant, much less dispositive, and its language – that "[t]he results of ***any*** scientific test should be repeatable at least three times" – strongly suggests that it was not. *Avon*, 984 F. Supp. at 787 (emphasis added).

[59] Plaintiffs' argument notably differs from Dr. Saed's proffered defense of his work, which was that it sufficed to measure his results three times. (*See* Defs.' Br. at 43.) Plaintiffs' unwillingness to defend Dr. Saed's explanation confirms its unreliability, and their effort to supplant it with alternative reasoning that he did not endorse could not save Dr. Saed's opinion under *Daubert* even if the alternative reasoning itself were not also flawed. *See Tamraz*, 620 F.3d at 671 (rejecting attempt to salvage expert's unreliable methods by reference to bases on which the expert's opinions did not rest).

cells), the *GPX1* mutation was only detected in five cell lines (not HOSEpiC cells), and the *NOS2* mutation was only detected in four cell lines (not A2780 or TOV112D cells).[60] Triplicate testing would have provided additional insight into whether these inconsistencies reflect spurious findings or whether the differences are attributable to some tested characteristic such as the cell line or the dose at issue. As it stands, Dr. Saed and the readers of his work can only guess, which does not suffice for *Daubert*.

F. Dr. Saed Relied On Irrelevant Cell Lines To Support His Conclusions On Ovarian Cancer Causation.

For the reasons explained in defendants' opening brief, Dr. Saed's use of irrelevant cell lines provides yet another basis to exclude his testimony.[61] Plaintiffs argue that Dr. Saed did use relevant cell lines and that, in any event, it does not matter what cell lines are used for purposes of demonstrating biological plausibility.[62] Plaintiffs are wrong on both counts.

First, plaintiffs' defense of Dr. Saed's cell lines is only partial insofar as they attempt to defend ***just one*** of the seven cell lines that Dr. Saed used – and even as to that cell line, their arguments fail. As noted in defendants' opening brief, Dr. Saed tested macrophage cells from the spleen, three lines of cancer cells,

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60 (Saed Rep. at 18-19.)

61 (Defs.' Br. at 44-46.)

62 (Pls.' Opp'n at 39-41.)

and immortalized fallopian tube and ovarian cells, none of which could serve as a model to show that talc could turn healthy ovarian or fallopian tube cells into cancer cells because the first four lines are not healthy ovarian or fallopian tube cells at all and because immortalized cells will not transform into cancer cells.[63] In response, plaintiffs attempt to defend just one of two ovarian cell lines Dr. Saed used, ignoring the other six cell lines and arguing that this one line was "human primary normal ovarian epithelial cells."[64] As such, it is undisputed that six of the seven lines Dr. Saed used could not provide a proper basis to support Dr. Saed's causal conclusions. And plaintiffs are wrong about the one cell line they do defend. As defendants explained in their opening brief – to no response from plaintiffs – Dr. Saed expressly testified that "the normal [cells he] used are immortalized cell lines" that "do not transform" and "do not change unless you really beat them up."[65]

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63 (Defs.' Br. at 45-46.)

64 (Pls.' Opp'n at 40.)

65 (Saed 2/14/2019 Dep. 464:13-17; 464:22-25; *see also* Defs.' Br. at 45 n.122.) At the end of this section of their brief, plaintiffs argue in a sentence that "immortalized cells . . . have been noted to be near the top of the hierarchy when it comes to relevance of experiments, just below primary human cells," citing *In re Rezulin Products Liability Litigation*, 369 F. Supp. 2d 398, 429 (S.D.N.Y. 2005). (Pls.' Opp'n at 41.) But this generalized description does not apply here because the non-transformable state of immortalized cells impedes the study of cancer development, making their use here improper despite their use in *Rezulin*, which

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Second, plaintiffs' contention that any cell line will do because Dr. Saed was not attempting to prove causation, but rather to provide "valuable insight" into the general causation inquiry,[66] also lacks merit. Even if it were correct that Dr. Saed's opinions were limited to biological plausibility, the use of the wrong cell lines still renders those opinions unreliable. To be relevant to the litigation – which is about the development of cancer in normal ovarian cells – there would have to be a reason to conclude that molecular changes in the cell lines Dr. Saed studied would take place in normal ovarian cells and cause cancer there, and neither plaintiffs nor Dr. Saed supplies such a reason. *See, e.g.*, *In re Rezulin*, 369 F. Supp. 2d at 429-30 (court excluding the molecular mechanism opinions of a proposed expert (along with the causation opinions of other experts) who relied on studies that failed to use relevant cell lines). Simply put, Dr. Saed studied the wrong cells, and plaintiffs' attempts to brush this error aside lack a scientific or legal basis.

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looked at the mechanisms underlying liver damage, which are not affected by the immortalized character of the cells.

66 (Pls.' Opp'n at 40-41.)

G. Dr. Saed's Reported SNP Findings Suggest Serious Methodological Flaws That Undermine His Conclusions On Causation And Biological Mechanism.

Defendants also explained in their opening brief that Dr. Saed's reported SNP results were nonsensical. Among other things, it is impossible for mutations to occur within 48 to 72 hours; the data generated by Dr. Saed's testing was clearly erroneous because although it was supposed to break down the genetic variants within a sample by percentage, the reported percentages added up to much more than 100% for certain samples; the results varied by cell type; and the results contradicted well-established literature that talc is not genotoxic.[67] Plaintiffs ignore much of this argument, focusing instead on deflecting attention from the impossibility that talc exposure could cause mutations within 72 hours, by arguing that: (1) Dr. Saed states only that talc "induced" mutations generally, not that the mutations themselves occurred within a 72-hour window; and (2) while the reviewers at *Gynecologic Oncology* expressed surprise at Dr. Saed's results, no other peer reviewer did.[68] These arguments lack merit.

First, plaintiffs retreat entirely from Dr. Saed's conclusion that treatment of cells with talc for 72 hours caused mutations by denying Dr. Saed's own words. They also fail to defend Dr. Saed's testing results that showed percentages in

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67 (Defs.' Br. at 46-52.)

68 (Pls.' Opp'n at 41-44.)

excess of 100%, to explain the inconsistency in results across cell lines or to reconcile Dr. Saed's results with literature concluding that talc is not genotoxic.

Rather than defend Dr. Saed's report on its own terms, plaintiffs suggest that Dr. Saed was merely inferring that mutations would occur based on changes in enzymatic activity.[69] But this statement cannot be reconciled with Dr. Saed's own pronouncements. Dr. Saed testified in no uncertain terms that "if you treat the cell line . . . with talc for 72 hours, there will be . . . an acquisition of this mutation."[70] Moreover, an entire table of Dr. Saed's published article is dedicated to reporting the results of "SNP Genotyping of Key Redox Enzymes in Untreated and Talc-Treated" cells, expressly reporting an "[a]mino acid switch" in certain "[c]hromosome location[s]."[71] In the text of his article, Dr. Saed similarly reports that the "[g]enotype [s]witches" in *NOS2*, *CAT* and *GPX1* were inconsistent across cell lines.[72] And when asked whether he could identify "any other substances that

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69 (*Id.* at 41-42.)

70 (Saed 1/23/19 Dep. 197:21-198:4.)

71 Fletcher et al., *Molecular Basis Supporting the Association of Talcum Powder Use With Increased Risk of Ovarian Cancer*, Reproductive Sciences 1, 7 tbl. 2 (2019) ("Saed Article") (attached as Ex. A39 to Tersigni Cert.).

72 *Id.* at 4 (emphasis omitted).

have been reported to ***cause mutations*** after 72 hours of treatment," Dr. Saed admitted that his results as reported were unprecedented.[73]

Defendants and their experts are not the only ones to understand what this plain language meant. The reviewers for *Gynecologic Oncology* similarly understood Dr. Saed to be claiming that brief talc treatment caused mutations – as evinced by their expression of "surpris[e]" that such rapid effect was possible.[74] Notably, Dr. Saed's response to that critique was to change the supposed 48-hour mutation period to 72 hours, presumably to make it more credible. Now, having learned from defendants' prominent cancer researchers that mutations within 72 hours would still be impossible, plaintiffs' counsel are retreating further, essentially abandoning the notion that Dr. Saed observed mutations at all.

Plaintiffs' suggestion that Dr. Saed was drawing from prior research to reach inferential conclusions[75] likewise holds no water. Dr. Saed has no "previous research" on the topic as he never conducted studies involving the administration

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[73] (Saed 1/23/19 Dep. 251:16-252:7.) Plaintiffs contend that earlier in his deposition, Dr. Saed attempted to differentiate between causing mutations within a short time frame and inducing mutations within a short time frame. (*See* Pls.' Opp'n at 42 (citing Saed 1/23/19 Dep. 251:4-14).) Noting about Dr. Saed's testimony suggested that he treated "cause" and "induce" as anything but the synonyms that they obviously are, and the distinction appears to have been entirely invented by plaintiffs' counsel.

[74] (Rejection Letter at 3.)

[75] (*See* Pls.' Opp'n at 41 (claiming that defendants "fail[ed] to consider the other research conducted by Dr. Saed, and referred to in his manuscript").)

of talc or any other particle to cell culture prior to being hired by plaintiffs.[76] The only study identified by plaintiffs is one in which Dr. Saed exposed cancer cells to chemotherapy drugs over a six-month period to isolate chemoresistant cells with *GPX1* mutations.[77] This study did not involve talc and offers no support for the notion that talc is capable of causing (or "inducing") SNP mutations. It is also irrelevant to the interpretation of protein expression and enzymatic activity data for the five unrelated genes (*CAT*, *SOD3*, *GSR*, *NOS2*, and *MPO*) examined by Dr. Saed here. In short, Dr. Saed clearly claimed that talc caused mutations in 72 hours, and the lengths to which plaintiffs have gone to attempt to retract that assertion shows that even they have no confidence in their expert's opinions.

Second, plaintiffs' effort to validate Dr. Saed's flawed SNP opinions by pointing to the fact that no abstract reviewers for the Society of Gynecologic Oncology ("SGO") raised questions about them[78] should also be rejected. Abstract review is not particularly rigorous – and there is notably no evidence that abstract reviewers supplied any feedback, positive or negative, regarding Dr. Saed's claimed SNP findings. The SNP abstract was also extremely brief, and did not

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[76] (Saed 1/23/2019 Dep. 29:17-21, 61:8-62:23.)

[77] Fletcher et al., *Specific point mutations in key redox enzymes are associated with chemoresistance in epithelial ovarian cancer*, 102 Free Radic Biol Med. 122 (2017) (attached as Ex. A185 to 2d Suppl. Tersigni Cert.).

[78] (Pls.' Opp'n at 43.)

include sufficient detail to enable searching review.[79] Moreover, when SGO did conduct a plenary review of Dr. Saed's finding, reviewing his manuscript submission at *Gynecologic Oncology*, the journal ***rejected*** those findings, highlighting the SNP findings specifically as "surprising" and in need of "further clarifi[cation]" and Dr. Saed's causal conclusions concerning talc as "insufficient[ly]" supported.[80] In short, there is no basis to conclude from the mere fact of acceptance of a single abstract that briefly summarizes Dr. Saed's claimed SNP findings that any reviewer agreed with the premise that 48 hours of talc treatment could cause mutations. For this reason, too, plaintiffs' efforts to defend Dr. Saed's opinions fail.

H. Dr. Saed's Lab Notebooks Demonstrate The Unreliability Of His Work.

Finally, as demonstrated in defendants' opening brief, Dr. Saed's lab notebooks, manuscripts and abstracts contain manifold errors that affect key issues such as treatment times, doses of talc used, the data underlying his opinions and even the identity of the product tested.[81] Plaintiffs assert that the irregularities

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79 The abstract at issue, which was submitted to the Society for Gynecologic Oncology, is about one page in length. (*See* Ex. B21 to Tersigni Cert.)

80 Rejection Letter at 2.

81 (Defs.' Br. at 52-55.)

found throughout Dr. Saed's work are "inadvertent" and "non-substantive,"[82] but they do not even address most of them – including the repeated errors concerning the key matters just noted. And the arguments that plaintiffs do make – concerning the curiously timed change of treatment time from 48 to 72 hours, Dr. Saed's use of white-out and his math errors – all lack merit.

First, plaintiffs' attempt to brush aside Dr. Saed's switch from 48 hours of treatment to 72 hours following the expressed "surprise" by the *Gynecologic Oncology* reviewer that such short treatment could cause mutations misses the point. Plaintiffs contend, in a footnote, that the "error is irrelevant" because it was never published, and in any event, Dr. Saed is not actually claiming that mutations occurred within either timeframe.[83] This argument overlooks the fact that Dr. Saed did publish abstracts reporting a 48-hour treatment time.[84] It also ignores that Dr. Saed's switch from reporting 48 hours of treatment to reporting 72 hours occurred immediately after the *Gynecologic Oncology* rejection. This chain of events – coupled with the fact that Dr. Saed changed the figures in his manuscript to reflect 72 rather than 48 hours of treatment ***without changing the data reflected in the***

82 (Pls.' Opp'n at 44.)

83 (Pls.' Opp'n at 46 n.152.)

84 (Defs.' Br. at 25.)

graphs[85] – strongly suggests that Dr. Saed was just making the treatment time up to avoid similar objections from future reviewers.[86]

Second, plaintiffs assert that Dr. Saed's use of white-out pertained merely to immaterial information.[87] But their only support for this assertion is Dr. Saed's *ipse dixit*.[88] As documented in defendants' opening brief, the white-out addressed important issues – including the dates of entries and the identity of the product being tested.[89] Plaintiffs neither deny this fact nor provide any explanation of how such fundamental issues could be immaterial. Nor does it make sense that a researcher would bother whiting out entries in a lab notebook if the errors were really immaterial, rather than simply crossing out the errors so that they remain visible, as is standard scientific practice.[90]

Third, plaintiffs assert that "[h]andwritten" mathematical errors in Dr. Saed's lab notebooks are of no moment because the data were stored electronically.[91] But the errors defendants identified were not handwritten; they

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85 (*Id.* at 25 (citing Mossman Rep. at 32).)

86 (*See id.*)

87 (Pls.' Opp'n at 44-45.)

88 (*Id.* at 44 (citing Saed 1/23/19 Dep. 100:5-13).)

89 (*See* Defs.' Br. at 17-18.)

90 (*See* Saed 1/23/19 Dep. 101:2-7.)

91 (Pls.' Opp'n at 45.)

were printed out from the very data that plaintiffs claim are electronically stored.[92] What the errors in these data indicate is that the computations were not done correctly because, as explained in the opening brief, simple averages were wrong.[93] The fact that such simple calculations were done incorrectly suggests they were performed manually or by erroneous computer formula (and however they were done, the point is the data are flawed). Plaintiffs address none of these points.

In short, Dr. Saed's prolific errors and alterations in his lab notebooks further highlight the unreliable nature of his work (and also raise further questions about the integrity of his process). For these reasons, too, his opinions should be excluded.

II. DR. SAED'S DATA, EVEN IF THEY WERE RELIABLE, WOULD NOT SUPPORT HIS CONCLUSIONS OR FIT THE FACTS OF THIS LITIGATION.

As defendants explained in their opening brief, Dr. Saed's data, even if they were reliable, would come nowhere close to supporting his conclusion that the Products can cause ovarian cancer – or support the biological plausibility of such a posited relationship – because there is a huge gap between his claimed findings and either of those two conclusions. Specifically, as the opening brief detailed, Dr. Saed himself acknowledged he would need to do animal studies in order to confirm

92 (Saed 1/23/19 Dep. 115:1 (cited in Pls.' Opp'n at 44); Defs.' Br. at 18-20 (citing SAED000022(color), SAED000033(color), and SAED000080(color)).)

93 (Defs.' Br. at 18-19.)

any biological effect from his work; there was no direct evidence that talc causes healthy cells to turn into cancer cells (nor could there be, since Dr. Saed decided not to test for such transformation); and Dr. Saed failed to provide any basis to link his reported findings regarding oxidative stress, SNP changes or CA-125 levels to ovarian cancer.[94]

Plaintiffs choose not to address many of these arguments, tacitly conceding them. Instead, they argue (again ignoring Dr. Saed's own words) that: (1) because Dr. Saed supposedly did not offer a causation opinion, he did not need to perform animal studies; (2) his results are supported by other prior research by him and others; and (3) the analytical gap between his findings and his causal conclusions is in any event an issue for a jury and not the Court to decide.[95] These arguments are seriously flawed for a host of reasons.

First, the scope of Dr. Saed's opinions is not nearly as modest as plaintiffs claim. His report states that "to a reasonable degree of scientific certainty" "***Johnson's Baby Powder exposure can cause ovarian cancer***."[96] Indeed, ***all but one*** of the six opinions that he offers deals ***directly*** with the development and progression of cancer supposedly induced by Johnson's Baby Powder; the other

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94 (Defs.' Br. at 55-75.)

95 (Pls.' Opp'n at 47-49.)

96 (Saed Rep. at 20 (emphasis added).)

deals with the issue indirectly.[97] As noted above, plaintiffs are not free to rewrite Dr. Saed's opinions to fix glaring admissibility problems in an opinion that overreaches. *See, e.g.*, *Tamraz*, 620 F.3d at 672-73; *In re Human Tissue*, 582 F. Supp. 2d at 667 (if an expert fails to adequately support his or her opinion, "counsel cannot fill in the gaps"); *In re Rezulin*, 369 F. Supp. 2d at 407 ("The subject of this motion is the proposed testimony of experts, not the theories of the lawyers.").

In any event, Dr. Saed's opinions also fail to establish biological plausibility. After all, neither Dr. Saed nor any other expert explains why the SNP changes that Dr. Saed claims to have identified or the increases in serum CA-125 levels purportedly establish biological plausibility. That gap would likewise compel exclusion of Dr. Saed's opinions. *See In re Rezulin*, 369 F. Supp. 2d 426-28; *see also In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 341 F. Supp. 3d

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[97] Opinion 1 is that Johnson's Baby Powder "***can result in the development and the progression of ovarian cancer***" (*id.* (emphasis added)); Opinion 2 regards the "pro-carcinogenic process" (*id.*); Opinion 4 involves dose-response, apparently in support of Dr. Saed's other opinions (*id.*); Opinion 5 is simply and flatly that "***Johnson's Baby Powder exposure can cause ovarian cancer***" (*id.* (emphasis added)); and Opinion 6 is that Johnson's Baby Powder "worsens the prognosis" for ovarian cancer patients (*id.* at 21). Only Opinion 3, which involves the elevation of CA-125 as "a clinically relevant biomarker for ovarian cancer" (*id.* at 20), can plausibly be construed as being limited to the opinion plaintiffs' counsel now offer for Dr. Saed.

213, 285 (S.D.N.Y. 2018) (excluding expert opinion because it "scarcely addresse[d]" the particular disease alleged in the litigation).

In re Rezulin is instructive. There, the court excluded a series of experts, including one expert, Dr. Reed, who did not expressly address causation and instead sought to offer testimony about evidence that Rezulin could induce apoptosis as purported "support for" the causation theories of other experts. *In re Rezulin*, 369 F. Supp. 2d at 408. In rejecting the opinion, the court explained that ***no*** expert presented reliable evidence that could take Dr. Reed's findings and "carry them all the way down their causal chain" to the injury at issue. *Id.* at 426-27. As a result, there was too great an analytical gap between the excluded expert's testimony and plaintiffs' theory of causation. *Id.* The same is true here: Dr. Saed provides a slate of purported findings, but no evidence bridging the gap between those findings and a conclusion of biological plausibility.

Second, and relatedly, the requirement that Dr. Saed conduct animal studies is not something that defendants made up and imposed on him; rather, it is a requirement of generally accepted scientific practice and ***one that Dr. Saed expressly acknowledged*** in his testimony[98] – a fact that plaintiffs nowhere acknowledge, much less attempt to explain away. Plaintiffs generally assert that

[98] (*See* Defs.' Br. at 57-58; Saed 2/14/19 Dep. 542:20-21 ("[T]o simulate that with what's going [on] *in[ ]vivo*, ***you have to do animal studies***.") (emphasis added); *see also* Saed 1/23/19 Dep. 333:7-9.)

Dr. Saed "does not have to do animal studies or replicate his results *in vivo*," but they cite no authority – legal, scientific, or otherwise – that supports this claim.

Plaintiffs cite one case to defend the use of *in vitro* studies in general, *Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co.*, 189 F. Supp. 2d 482 (S.D. W. Va. 2002),[99] but that case supports defendants (and was extensively cited in their brief). *Bourne* ***excluded*** expert testimony – even though animal testing ***had*** been done – because of the absence of "supporting epidemiological studies, ***testing on closely related species, and the use of comparable dosages***." *Id.* at 496-99 (emphasis added) (footnote omitted). Plaintiffs also cite the Reference Manual on Scientific Evidence for the proposition that no concrete rules govern the reconciliation of *in vitro* and epidemiological data,[100] but the portion of the *Reference Manual* that they cite refers to reconciling epidemiology with ***animal*** studies, not *in vitro* studies; it does not purport to obviate the necessity of conducting animal studies or suggest that mere *in vitro* findings can stand in for such work.[101] If anything, the *Reference Manual* suggests the opposite, since elsewhere it expressly cautions against undue reliance on *in vitro* work,

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99 (Pls.' Opp'n at 47 & n.159.)

100 (Pls.' Opp'n at 48 & nn.160-62.)

101 Epidemiology Reference Manual at 564 ("Where both ***animal*** toxicologic and epidemiologic studies are available, no universal rules exist for how to interpret or reconcile them") (emphasis added) (quoted without the word "animal" in Pls.' Opp'n at 48).

admonishing that while there are "short-term in vitro tests for just about every physiological response and every organ system," "[r]elatively few of these tests have been validated . . . by comparison with outcomes in animal studies to determine if they are predictive of whole animal or human toxicity," and emphasizing the importance of establishing that *in vitro* tests are in fact "predictive of in vivo outcomes,"[102] something Dr. Saed admittedly did not attempt here. In short, nothing supports the notion that Dr. Saed's findings have significance in the absence of replication in an animal study.

Third, plaintiffs' reference to Dr. Saed's "other experiments" or "the body of literature related to talcum powder products"[103] is meaningless because they do not cite a single experiment or source from the literature, let alone one that could serve as a bridge between Dr. Saed's purported findings concerning oxidative stress, SNPs or CA-125 and ovarian cancer.

While Dr. Saed's report and article cite other sources, these sources do not bridge that gap either. For example, Dr. Saed's report discusses the SNPs that he claims are associated with ovarian cancer, but ***none of these*** is among the SNPs

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102 *Id.* at 645-46.

103 (Pls.' Opp'n at 48-49.)

that he examined in his experiment.[104] Dr. Saed very briefly mentions literature discussing CA-125 levels, but while CA-125 can be elevated in women with ovarian cancer, none of the literature suggests that CA-125 causes ovarian cancer, and Dr. Saed does not argue otherwise.[105] And while Dr. Saed extensively discusses literature on chemotherapy resistance,[106] that topic is utterly irrelevant to this litigation and only one of Dr. Saed's six conclusions so much as touches on that issue.

Fourth, plaintiffs' contention that it is beyond this Court's purview to ascertain whether there is a gap between Dr. Saed's findings and his conclusions[107] is clearly wrong as a matter of law. It is axiomatic that a court need not "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert" and that it should exclude evidence if there is "too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. Plaintiffs' contention that this is not a proper basis for exclusion because it focuses on conclusions rather than methods is ***precisely*** the argument that was raised and

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104 (*See* Saed Rep. at 7-9 (discussing SNPs purportedly associated with ovarian cancer).)

105 Indeed, Dr. Saed repeatedly admitted that he has no expertise as it relates to CA-125. (*See, e.g.*, Saed 1/23/19 Dep. 248:5-8 (Dr. Saed admitting he does not know whether CA-125 is used to diagnose or determine the cause of ovarian cancer).)

106 (*See* Saed Rep. at 9-10.)

107 (Pls.' Opp'n at 49-50.)

rejected in *Joiner*. *Id.* (rejecting argument that the district court improperly excluded evidence based on "disagreement" with "conclusion[s]," explaining that "conclusions and methodology are not entirely distinct from one another").

Plaintiffs' cases are not to the contrary. *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11 (1st Cir. 2011) (cited in Pls.' Opp'n at 49 & n.165), acknowledges the *Joiner* principle and merely held that the district court misapplied it based on a "mistake in its understanding of the . . . [expert's] methodology." *Id.* at 22-23. And *Kannankeril v. Terminix International, Inc.*, 128 F.3d 802 (3d Cir. 1997) (cited in Pls.' Opp'n at 49-50 & nn.166, 168) – a case that not only predates the Supreme Court's decision in *Joiner*, but relies upon the very 11th Circuit decision that *Joiner* reversed – is not a case about the analytical gap between data and conclusions at all. *See id.* at 809 (citing *Joiner v. Gen. Elec. Co.*, 78 F.3d 524, 534 (11th Cir. 1996), *rev'd*, 522 U.S. 136). Rather, it stands for the unremarkable proposition that conflicts in the evidence are for the trier of fact.[108]

In short, Dr. Saed's findings do not speak for themselves. He or someone else must bridge the gap between those findings and a conclusion of biological

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[108] *In re Actos (Pioglitazone) Products Liability Litigation*, No. 12-cv-00064, 2014 WL 60324 (W.D. La. Jan. 7, 2014) (cited in Pls.' Opp'n at 50 n.168) is even less on point. The portion quoted in plaintiffs' brief defends an expert against a charge of "cherry-picking," which has no bearing on this argument.

plausibility, and neither Dr. Saed nor any other expert has done so. For this reason, too, his opinions should be excluded.

III. BECAUSE VITAL INFORMATION WAS HIDDEN, DR. SAED'S WORK HAS NEVER BEEN PROPERLY PEER REVIEWED.

Finally, as explained in defendants' opening brief, Dr. Saed manipulated the peer-review process by repeatedly omitting and misrepresenting his status as a paid litigation expert and by failing to disclose or meaningfully respond to the criticisms of the *Gynecologic Oncology* reviewers when resubmitting his manuscript to *Reproductive Sciences*, which accepted it for publication.[109] Plaintiffs contend that Dr. Saed made all relevant financial disclosures and that *Gynecologic Oncology* and other reviewers held his work in "high regard," leaving nothing to disclose to *Reproductive Sciences*.[110] These arguments grossly distort the relevant record.

First, plaintiffs contend that "at no time did Dr. Saed 'misrepresent' the nature of his funding as posited by Defendants" and that he "provided the conflict information that was required" at each stage of the process.[111] That is not correct, for all the reasons already set forth in defendants' opening brief, most notably that the published version of Dr. Saed's article ***still*** falsely claims that he "received no

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109 (Defs.' Br. at 75-79.)

110 (Pls.' Opp'n at 50-55.)

111 (*Id.* at 51.)

financial support for the research, authorship, and/or publication of this article."[112] This statement is not merely an omission; it is an outright misrepresentation. Dr. Saed testified that he was compensated for the 60 to 70 hours he spent writing the manuscript by plaintiffs' counsel. At the $600 hourly rate they were paying him, that works out to $36,000 to $42,000.[113] ***Plaintiffs do not even attempt to address this misrepresentation in their brief***, even though they stress another, different disclosure in the same article.[114] And while plaintiffs contend that arguments concerning "financial interests" generally go to the weight rather than admissibility of testimony,[115] the situation is different here in light of Dr. Saed's persistent failure to provide adequate disclosures and the ongoing misinformation in the published version of his article.

Second, plaintiffs' assertion that the reviewers of *Gynecologic Oncology* and the "twenty reviewers and editors" who read Dr. Saed's abstracts all expressed "high regard" for his work[116] also badly mischaracterizes the record. With respect to *Gynecologic Oncology*, the actual rejection letter from the journal cannot be

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112 (Defs.' Br. at 77 (quoting Saed Article at 9); *see also id.* at 76-77 (detailing the omission of funding detail at every other step of the publication process).)

113 (Defs.' Br. at 21, 77.)

114 (*See* Pls.' Opp'n at 52 & n.175.)

115 (*Id.* at 52.)

116 (Pls.' Opp'n at 53-55.)

reconciled with this rosy description. Plaintiffs contend, for example, that the reviewers generally believed that Dr. Saed's conclusions as to the causation of ovarian cancer were "***supported by [his] results***,"[117] but that is not true. The same reviewer expressly indicated that "the cell line studies alone and the increase in CA-125 . . . are ***not sufficiently convincing***" and, crucially, told Dr. Saed to remove his top-line reference to ovarian cancer because it was "***not supported by this investigation and should be omitted***."[118] The second reviewer was, if anything, more explicit, writing that "the present data are insufficient to back up the claim that talc[] is central to the development of ovarian cancer."[119]

Plaintiffs' counsel's comfort in the "twenty reviewers and editors" of Dr. Saed's abstracts is once again *ipse dixit*, since plaintiffs have not produced a single statement by any of these reviewers praising Dr. Saed's work. Having testified that the reviewers at *Gynecologic Oncology* loved his work, Dr. Saed (and plaintiffs' counsel) cannot be taken at their word when it comes to the reception of Dr. Saed's work. In any event, not all peer review is created equal. *Valentine v. Pioneer Chlor Alkali Co.*, 921 F. Supp. 666, 675 (D. Nev. 1996) ("[I]t is a serious error . . . to assume that because an article is accepted for publication . . . that the

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117 (*See id.* at 54 (quoting Rejection Letter at 3).)

118 (Rejection Letter at 2 (emphases added).)

119 (*Id.*)

science it contains is therefore valid."; "This is especially true at journals below the very first rank . . . ."); *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 778 (D. Md. 2002) ("The fact of publication, of course, does not eliminate the need to examine the results and methodology of the study . . . ."), *aff'd*, 78 F. App'x 292 (4th Cir. 2003) (per curiam). The quality can "rang[e] from [peer reviews] which are worthless to those which are of high quality." *Black*, 19 F. Supp. 2d at 600. Abstract review does not rank on the high end. As Dr. Neel explained, an abstract will likely be accepted if it is "written in English."[120] And this is no surprise. Even if the reviewers of an abstract wanted to carefully inspect an author's methods, data and conclusions, an abstract simply does not provide the information necessary for them to do so. For example, Dr. Saed's abstract for the Society for Reproductive Investigation described his methods in a few short sentences, described his results in two sentences that were devoid of any graphs or tables, and then offered the conclusory statement that those results "provide a molecular basis" linking cosmetic talcum powder to ovarian cancer.[121]

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[120] (Neel Dep. 341:7-10.)

[121] Fletcher et al., *LB-044 – Talcum Powder Enhances Cancer Cell Antigen 125 Levels in Ovarian Cancer Cells and in Normal Ovarian Epithelial Cells*, Society for Reproductive Investigation (2018) (Saed 1/23/19 Dep. Ex. 21) (attached as Ex. B18 to Tersigni Cert.). Moreover, Dr. Saed's work itself amply demonstrates how limited the peer review of abstracts can be. As he admitted at his deposition, the Society for Reproductive Investigation accepted his bare-bones abstract and he went on to present a poster at their conference that wrongly claimed that certain

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Finally, it is likewise of no help to plaintiffs that Dr. Saed ultimately published in *Reproductive Sciences* – which is edited by a close colleague of Dr. Saed's frequent co-author, Dr. Michael Diamond.[122] As established above, much of the information that the *Reproductive Sciences* reviewer would have needed to adequately evaluate it was hidden – either because of Dr. Saed's misrepresentations or because of the nature of the peer-review process. Many of the flaws that defendants have identified in Dr. Saed's work – e.g., his decision to change all of his 48-hour treatment times to 72 hours, the errors that litter his laboratory notebooks and his failure to follow his own stated methodology – would not have been available to the journal reviewer. This is so because the review process presupposes that the submitting scientist has taken such basic steps as accurately recording his or her data. And in any event, Dr. Saed's manuscript is more circumspect in its claims than his report in this litigation, which, as noted above, contains express causal conclusions – conclusions that are nowhere contained in the published article.

In short, to this day, there is no indication that *Reproductive Sciences* has ever been told that Dr. Saed's article was bought and paid for to the tune of tens of

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findings were statistically significant when his own lab notebooks revealed that they were not. (*See* Saed 2/14/19 Dep. 403:3-407:8.)

[122] (Defs.' Br. at 26.)

thousands of dollars (or that he has been paid hundreds of thousands of dollars for additional work) by plaintiffs' counsel with a vested interest in having Dr. Saed's article and conclusions published. Because the normal peer-review process was corrupted, any consideration of peer review should weigh heavily ***against*** the admissibility of Dr. Saed's opinions.

CONCLUSION

For the foregoing reasons, and those set forth in defendants' opening brief, the Court should exclude evidence of Dr. Saed's experiments, his manuscript and his opinions.

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Respectfully submitted,

Susan M. Sharko

Susan M. Sharko
DRINKER BIDDLE & REATH LLP
600 Campus Drive
Florham Park, New Jersey 07932
Telephone: 973-549-7000
Facsimile: 973-360-9831
E-mail: susan.sharko@dbr.com

John H. Beisner
Jessica D. Miller
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
202-371-7000

Attorneys for Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.